UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., *Plaintiff*, v. BIONPHARMA INC., *et al*., *Defendants*.	C.A. No. 21-1286-MSG (consolidated) **REDACTED - PUBLIC VERSION**

DEFENDANT BIONPHARMA'S LETTER REQUESTING AN ORDER COMPELLING PLAINTIFF AZURITY TO PROVIDE DISCOVERY CONCERNING ITS ANTITRUST DOCUMENT COLLECTION EFFORTS

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Pursuant to Court order (D.I.[1] 330, 6/5/23 Hr'g Tr. 35:20-36:1) Defendant Bionpharma submits the instant letter requesting an order compelling Plaintiff Azurity to produce: (1) a declaration from one of its senior executives explaining its antitrust document collection efforts in these cases and (2) a Rule 30(b)(6) witness to testify on those collection efforts.

INTRODUCTION AND SUMMARY OF FACTS

Fifteen months after Bionpharma served its antitrust RFPs, and over two months after Azurity stated that it would produce, or search for and produce, documents in response to 30 of those RFPs,[2] Azurity's June 2 letter to the Court (D.I. 325) reveals for the first time its claim that it has no further antitrust-specific documents. Since Azurity began filing these Third Wave Suits in June 2021, it has produced approximately 922 documents for a total of approximately 17,936 pages. Ex. A, 6/9/23 Shrestha Decl. ¶ 3. The vast majority of this production—approximately 15,416 pages—relates to the patent issues in these cases, such as prosecution histories for the patents-in-suit and related patents, lab notebooks, and invalidity/infringement documents (such as transcripts and expert reports) from related cases (*e.g.*, against Alkem, Annora), leaving less than about 2,520 pages of antitrust-specific documents. *Id.* ¶ 5.[3]

As explained during the June 5, 2023 teleconference with the Court, Bionpharma has reason to believe that Azurity's search for antitrust-specific documents in its possession, custody, or control was deficient. Indeed, certain documents that Azurity has produced in these suits strongly suggest that Azurity should have, but has failed to produce, documents concerning generic competition to Epaned; communications between Azurity and either NovaQuest (its parent (D.I. 135, Bionpharma's CCLS ¶¶ 16-19)) or CoreRx (its corporate sister (*id.*)) concerning the patents-in-suit, Epaned, Bionpharma, and Bionpharma's ANDA product; and documents concerning Azurity's decision to sue Bionpharma for alleged infringement of nine related patents over three waves of litigation. Outside of documents concerning the "settlement" of Azurity's suit against CoreRx, Azurity has failed to produce any email communications (Ex. A, 6/9/23 Shrestha Decl. ¶ 7), which in and of itself renders Azurity's search suspect. Bionpharma respectfully requests that Azurity be ordered to serve a declaration from a senior executive explaining its antitrust document collection efforts and to produce a corporate witness to answer questions regarding its document collection efforts.

ARGUMENT

I. AZURITY'S DOCUMENT COLLECTION EFFORTS ARE SUSPECT

Azurity's supplemental responses to Bionpharma's antitrust RFPs, served a little over two months ago, represented that it would produce, or search for and produce, numerous categories of

[1] All "D.I." citations are to the 21-1286 docket unless otherwise specified, and all abbreviations not defined herein have the meaning ascribed in the Table of Abbreviations set forth in Bionpharma's Opposition to Azurity's Motion to Dismiss (D.I. 155).

[2] D.I. 321-3, Bionpharma's 6/1/23 Ltr. Ex. C, Supplemental Resps. to RFP ("SR to RFP") Nos. 11-14, 20-25, 27-29, 44-47, 49-51, 53-58, 60, 63-66.

[3] Azurity has produced more than 166 slip-sheets for documents it has withheld in their entirety allegedly on privilege grounds.

antitrust-specific documents, only to turn around and proclaim in its June 2, 2023 letter to the Court (D.I. 325) that it has no further antitrust-specific documents to produce. D.I. 325, Azurity's 6/2/23 Ltr. at 2. But certain factual circumstances and documents that the parties have produced strongly suggest otherwise.

For instance, Azurity represented that it would produce all documents and things relating to actual or potential generic competition to Epaned. D.I. 321-3, SR to RFP No. 21). Such documents would include internal emails and correspondence regarding Bionpharma's ANDA product, Alkem's ANDA product (C.A. No. 19-2100-MSG), Annora's ANDA product (C.A. No. 21-196-MSG), Aurobindo's ANDA product (CA. No. 21-1707-MSG), competitive intelligence documents, market analyses (including industry analysis, product analysis, competition/competitor analysis, SWOT analysis, market forecast) documents, and product budget documents. Azurity has produced two 2022 quarterly "performance summar[ies]" (Ex C, SLVGT-EPA_0112220-54; Ex. D, SLVGT-EPA_0112173-219) and one November 2021 "product performance" presentation (Ex. E, SLVGT-EPA_0112255-91); and two documents from late 2022—a 2022 forecast summary (Ex. F, SLVGT-EPA_0122800-48), and a November 2022 budget presentation (Ex. G, SLVGT-EPA_0122776-99). Not one document relating to Azurity's launch, to Azurity's assessment of competition prior to or immediately upon Bionpharma's launch, or to Azurity's three waves of suits against Bionpharma. And not a single e-mail on any of these subjects, other than e-mails between Azurity and its sister company CoreRx concerning the "settlement" of Azurity's lawsuits against CoreRx. Exhibits C-G contradict Azurity's assertion that it has no further antitrust specific documents. Even this handful tends to confirm that, just like any pharmaceutical manufacturer owned by sophisticated private equity firm, Azurity must have generated any number of quarterly or annual strategic documents assessing its past Epaned sales and planning for the future of its franchise. And this says nothing about the e-mails that were bound to travel among Azurity's directors, executives and employees on these subjects. Azurity does not try to explain this deficiency. Instead, it falls back on the irrelevant evidentiary overlap between the antitrust and patent claims as to objective baselessness, and seems to award itself summary judgment: because, as it mistakenly asserts, Bionpharma's ANDA filing justified its filing and continued maintenance of its suits—even after it knew or should have known that its suits were unsupportable on the merits—it is entitled to deny Bionpharma discovery on the other antitrust issues. Azurity's apparent belief that it will succeed on objective baselessness, even if it were correct, cannot overcome Azurity's right to obtain this crucial discovery.

Next, Azurity represented on March 28 that it would produce, or search for and produce, documents and communications between Azurity and either NovaQuest or CoreRx concerning the patents-in-suit, Epaned, Bionpharma, and Bionpharma's ANDA product. D.I. 321-3, SR to RFP Nos. 14, 22-24. But outside of emails between Azurity and CoreRx concerning "settlement" of the sham CoreRx Suits, Azurity has produced no email correspondence between itself and NovaQuest and CoreRx. Although Azurity asserts that NovaQuest is merely an "invest[or] in…portfolio companies" that "was not involved in the day-to-day operations" of Azurity (D.I. 330, 6/5/23 Hr'g Tr. at 11:19-22, 12:20-21; *see also* D.I. 322 at 3), documents Azurity itself has produced belie its assertion, including agendas for monthly calls between NovaQuest and Azurity. *See* Ex. B, SLVGT-EPA_0123169-81. The December 9, 2020 Agenda is particularly revealing, as it shows that Azurity and NovaQuest discussed Bionpharma, new enalapril patents Azurity had obtained, and the upcoming February 2021 First Wave Suits trial. *Id*. at SLVGT-EPA_0123170; *see also id*. at SLVGT-EPA_0123177 (Aug. 2020 Agenda) and SLVGT-EPA_0123179 (Sept.

2020 Agenda). Further, as mentioned in Bionpharma's June 2 letter (D.I. 324 at 2), Bionpharma itself has produced email correspondence showing NovaQuest partners who are board members at Azurity and CoreRx taking an active, hands-on role in managing both sibling companies, including: (1) negotiating agreements with Bionpharma on behalf of CoreRx during the pendency of the First and Second Wave Suits, and approximately 9 months prior to the filing of the CoreRx Suits (D.I. 326-1, BION-ESOL-00040442-56 (involving Poole and Edwards)); and (2) attempting to negotiate settlement of the Third Wave Suits with Bionpharma on behalf of Azurity (D.I. 326-2, BION-ESOL-00090124-25; D.I. 326-3, Ex. C, BION-ESOL-00106754-55 (Edwards)). This active, hands-on management by NovaQuest suggests that Azurity has carried out a faulty search for documents, and that there are likely correspondence in Azurity's possession, custody, or control between Azurity and NovaQuest and/or CoreRx pertaining to the antitrust issues in these cases that it has improperly withheld or failed to locate.

Finally, yet another example of antitrust-specific documents that Azurity represented on March 28 it would search for and produce, only to retreat now from that representation, are documents concerning its decision to sue Bionpharma for alleged infringement of nine related patents over three waves of litigation. D.I. 321-3, SR to RFP Nos. 64-66. Bionpharma and Azurity have been litigating Bionpharma's ANDA and Azurity's enalapril liquid patent family for the last four and a half years, and it appears—from its failure to produce market analyses and budget documents for years prior to 2021, and its failure to produce internal emails and correspondence (outside of its production concerning the shame CoreRx Suits)—that Azurity may have improperly restricted the temporal scope of its search to only go back to June 2021 (the filing of the First of the these Third Wave Suits). This would be improper as Bionpharma has alleged anticompetitive conduct going back to 2018. D.I. 135, CCLS ¶¶ 63-98. Azurity's claim that it has nothing (besides, presumably, its patent production) in response to Bionpharma RFP Nos. 64-66 is entirely suspect.

II. AZURITY SHOULD BE ORDERED TO ACCOUNT FOR ITS DOCUMENT COLLECTION EFFORTS

"As [the Third Circuit] ha[s] often said, matters of docket control and discovery are committed to broad discretion of the district court." *United States v. Washington*, 869 F.3d 193, 220 (3d. Cir. 2017); *see also Hall v. Johnson & Johnson*, C.A. No. 18-1833 (GC), 2022 WL 1284466, at *3 (D.N.J. Apr. 29, 2022) ("[A]s always, the Court has broad discretion in managing requests for discovery and determining the appropriate scope of discovery."). This Court has the authority to order a party to provide a declaration from an in-house representative explaining document collection efforts and to order a party to produce a corporate witness to testify as to the party's document collection efforts. *See, e.g., Target Corp. v. ACE Am. Ins. Co.*, 576 F. Supp. 3d 609, 621-22 (D. Minn 2021); *Altair Instruments, Inc. v. Telebrands Corp.*, Case No. 2:19-cv-08967-PSG-JC, 2021 WL 5260300, at *1 (C.D. Cal. Aug. 19, 2021). Azurity should be required to do so here, as its production of only about 2,520 pages of antitrust-specific documents is highly unusual in a sprawling patent and antitrust dispute such as the instant one, which involves conduct going back to 2018. Given the high stakes in these cases and the burden Bionpharma has in proving its antitrust claims (including producing evidence on Azurity's subjective bad faith, its degree of market power, the intended and expected effect of its suits against Bionpharma, and the causal link between its exclusionary conduct and harm to Bionpharma and consumers), Bionpharma respectfully submits that it should be able to probe Azurity's antitrust document collection efforts in these cases, and requests the Court's assistance in doing so.

Dated: June 8, 2023

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CERTIFICATE OF SERVICE

I, Megan C. Haney, hereby certify that on June 8, 2023, a copy of Defendant Bionpharma's Letter Requesting an Order Compelling Plaintiff Azurity to Provide Discovery Concerning Its Antitrust Document Collection Efforts was served upon the following counsel of record in the manner indicated below:

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